

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

DAYTON AREA CHAMBER OF COMMERCE, *et al*,

Plaintiffs,

v.

XAVIER BECERRA, U.S. Secretary of Health &
Human Services, *et al.*,
Defendants.

Civil Action No. 3:23-cv-00156

Judge Michael J. Newman
Magistrate Judge Peter B. Silvain, Jr.

CONSENT MOTION OF THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE
AMERICAN COLLEGE OF PHYSICIANS, THE SOCIETY OF GENERAL INTERNAL
MEDICINE, THE AMERICAN GERIATRICS SOCIETY, AND THE AMERICAN
SOCIETY OF HEMATOLOGY
FOR LEAVE TO FILE AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-
MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT

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Proposed *amici* American Public Health Association, the American College of Physicians, the Society of General Internal Medicine, the American Geriatrics Society, and the American Society of Hematology move for leave to file the attached *amicus* brief in opposition to the motion for summary judgment filed by Plaintiffs Dayton Area Chamber of Commerce, Ohio Chamber of Commerce, Michigan Chamber of Commerce, and the Chamber of Commerce of the USA (“Plaintiffs”) and in support of Defendants’ motion for summary judgment. Counsel for the Parties consent to this motion.¹

The Court should exercise its “sound discretion” to allow proposed *amici*, who bring substantial and unique expertise to the public health issues at the center of this case. *United States v. State of Mich.*, 940 F.2d 143, 165 (6th Cir. 1991). “[A]n *amicus* brief should be allowed when the *amicus* has unique information or perspective that can help the court beyond that the lawyers or the parties are able to provide.” *U.S. ex rel. Roby v. Boeing Co.*, 73 F.Supp.2d 897, 900 (S.D. Ohio 1999); *see also United States v. City of Columbus, Ohio*, No. CIV.A. 2:99-CV-1097, 2000 WL 1745293, at *1 (S.D. Ohio Nov. 20, 2000) (allowing *amicus* participation where the “issues presented . . . are matters of great public interest and concern, both to the parties, to the proposed *amici*, and to the public at large”); *Sigetich v. Kroger Co.*, No. 1:21-CV-697, 2022 WL 2900766, at *3 (S.D. Ohio July 22, 2022) (granting the US Chamber of Commerce, a Plaintiff here, leave to file an *amicus* brief where “it had an important interest and a valuable perspective on the issues presented”) (cleaned up). Proposed *amici* are some of the preeminent professional organizations in the country that focus on public health and patient outcomes. This case, relating to one of the nation’s largest public health programs, with

¹ Plaintiffs’ counsel consented “assuming that” proposed *amici*’s brief would be filed before December 22, 2023. So that the Court and Plaintiffs’ counsel have access to the proposed *amicus* brief ahead of December 22, proposed *amici* have appended a copy of their proposed brief to this motion.

implications for the long-term health of tens of millions of Americans, falls squarely within proposed *amici*'s professional interests and expertise. Proposed *amici*'s brief provides facts, insight, and data not to be found in the Parties' briefs, in that it provides detailed public health analysis that is absent from the Parties' respective briefs.

IDENTITY AND INTERESTS OF PROPOSED *AMICI CURIAE*²

American Public Health Association

The American Public Health Association (APHA) is a professional public health organization with over 26,000 members across the globe, working in 33 distinct public health disciplines or programs.³ APHA aims to improve health equity in the U.S. by producing peer-reviewed public health research, developing programs to reduce healthcare disparities, and advocating for equitable, evidence-based health policy.

Since 1948, APHA has developed and maintained a policy database with hundreds of statements that analyze health policies and provide recommendations supported by scientific evidence.⁴ APHA policy statements, developed and reviewed consistent with scientific and ethical guidelines, have addressed prescription drug spending and its effects repeatedly.⁵ APHA

² Proposed *amici curiae* certify that no Party or Party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission.

³ Am. Pub. Health Ass'n, *Frequently Asked Questions*, <https://www.apha.org/Membership/Frequently-Asked-Questions> (choose "What is an APHA Section?") (last visited Nov. 6, 2023).

⁴ See Am. Pub. Health Ass'n, *Policy Statement Database*, <https://www.apha.org/Policies-and-Advocacy/Public-Health-Policy-Statements/Policy-Database> (last visited Nov. 6, 2023).

⁵ See, e.g., Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* (Nov. 8, 2022), <https://www.apha.org/Policies-and-Advocacy/Public-Health-Policy-Statements/Policy-Database/2023/01/18/Affordable-Prescription-Medications>; Am. Pub. Health Ass'n, *Regulating Drugs for Effectiveness and Safety: A Public Health Perspective* (Nov. 8, 2006), <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/18/09/17/regulating-drugs-for-effectiveness-and-safety-a-public-health-perspective>; Am. Pub. Health Ass'n, *Creating The Healthiest Nation: Advancing Health Equity*, https://www.apha.org/-/media/Files/PDF/factsheets/Advancing_Health_Equity.ashx (last visited Nov. 6, 2023); Am. Pub. Health Ass'n, *Ensuring That Trade Agreements Promote Public Health* (Nov. 13, 2015),

regularly serves as an *amicus* in cases that may affect public health.⁶ Its briefs have been cited approvingly by the Supreme Court.⁷ APHA has publicly supported the government program at issue in this case.⁸

American College of Physicians

The American College of Physicians (ACP) is the United States' largest professional medical society of physicians who specialize in internal medicine. With over 161,000 physicians and subject matter experts across the globe, ACP members apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults.⁹

The ACP advocates for improving population health and well-being by promoting inclusive and equitable healthcare access in the United States.¹⁰ It has provided scientific evidence and professional expertise in more than thirty *amicus* briefs to advocate for issues important to internal medicine physicians and their patients.¹¹ Organization members of the ACP have addressed issues related to coverage and cost of care, Medicare and Medicaid policy

<https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2015/12/08/16/04/ensuring-that-trade-agreements-promote-public-health>.

⁶ See, e.g., Br. of Wisconsin Medical Society et al. in Supp. of Plaintiff-Appellee and Affirmance, *Loertscher v. Anderson*, 259 F.Supp.3d 902 (W.D. Wis. 2017).

⁷ See, e.g., *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 729 n.6 (1985); *Ferguson v. City of Charleston*, 532 U.S. 67, 78 (2001); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 248-49 (2011) (Breyer, J., concurring).

⁸ See Am. Pub. Health Ass'n, *APHA Applauds Senate Passage of Inflation Reduction Act* (Aug. 8, 2022), <https://www.apha.org/News-and-Media/News-Releases/APHA-News-Releases/2022/Inflation-Reduction-Act>.

⁹ Am. Coll. Physicians, *Who We Are*, <https://www.acponline.org/about-acp/who-we-are> (last visited Sept. 12, 2023).

¹⁰ Am. Coll. Physicians, *Access to Care*, <https://www.acponline.org/advocacy/where-we-stand/access-to-care> (last visited Nov. 6, 2023).

¹¹ See, e.g., Br. of Amici Curiae American College of Physicians et al. in Supp. of Resps., *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022) (No. 19-1392); Mot. for Leave to File & Br. of American Medical Association et al. as Amici Curiae in Opp'n to Appls. for Stay, *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 142 S. Ct. 661 (2022) (No. 21-A-244).

changes, healthcare payment systems, and more. The ACP has submitted comments on the government program at issue in this case.¹²

Society of General Internal Medicine

The Society of General Internal Medicine (SGIM) is a member-based association of more than 3,300 of the world's leading academic general internal medicine physicians, who are dedicated to delivering comprehensive, coordinated, and cost-effective care to adults, educating the next generation of outstanding physicians, and conducting cutting-edge research to improve quality of care and clinical outcomes of all patients. It has a vision for a just system of care in which all people can achieve optimal health. Accordingly, SGIM has long advocated for sustainable prescription drug pricing, including by joined the Campaign for Sustainable Rx Pricing (CSRxP) in 2016, because the high cost of prescription drugs is one of most difficult challenges patients face.

American Geriatrics Society

The American Geriatrics Society (AGS) is a national non-profit organization of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of all older Americans. Its more than 6,000 members include geriatricians, geriatrics nurse practitioners and advanced practice nurses, social workers, family practitioners, physician assistants, pharmacists, and internists, all of whom are pioneers in advanced illness care for older individuals. AGS has worked tirelessly to ensure that older adults and individuals with Medicare have access to interprofessional care teams dedicated to eliciting personal care goals and treating

¹² William Fox, *ACP Comments on CMS' Proposed Changes to Medicare Advantage and Part D*, Am. Coll. Physicians 7 (Feb. 13, 2023), https://assets.acponline.org/acp_policy/letters/acp_comments_on_cms_proposed_changes_to_medicare_advantage_and_part_d_2023.pdf.

older people as whole persons. As part of that mission, AGS has long advocated that older adults have access to medically necessary, appropriate, and affordable medications that align with individuals' care goals and clinically supervised medication management to reduce risks of unnecessary polypharmacy. Since 2011, the AGS has been the steward of the AGS Beers Criteria® for Potentially Inappropriate Medication (PIM) Use in Older Adults, a regularly updated resource that is widely used by clinicians, educators, researchers, healthcare administrators, and regulators.

American Society of Hematology

The American Society of Hematology (ASH) represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders as well as classical (non-malignant) conditions. ASH believes that all individuals should have access to and be able to afford high-quality, clinically appropriate care. High drug prices continue to be a major issue facing patients with hematologic diseases and disorders, and ASH continues to identify and advocate for ways to limit patient out-of-pocket expenses.

RELEVANCE TO THE COURT

Plaintiffs allege that the drug price negotiation program ("Program") of the Inflation Reduction Act, that allows the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices for Medicare, 42 U.S.C. §§1320f(d) *et seq.*, violates various provisions of the U.S. Constitution and the Administrative Procedures Act. *See* Am. Compl., ECF No. 57 ("Compl."). In so alleging, Plaintiffs makes certain representations regarding the nature, history, and viability of the Medicare program, and of the role of prescription drugs in public health. *See, e.g., id.* ¶¶ 7, 61-71, 155; Pls.' Br. in Support of Summ. J., ECF No. 64 ("Pls.' Br."), at 6-7. Plaintiffs also suggest that the Program will harm public health, in part by harming innovation. *See, e.g.,*

Compl. ¶¶ 7, 8, 23, 68-71, 153-54; Pls.’ Br. at 19, 25-26. Plaintiffs recently argued that doctors and patients may be harmed by the Program and thus may support drug manufacturers’ efforts to gut the Program. *See* Sept. 15, 2023, Transcript of Oral Arg. on Pls.’ Mot. for Prelim. Inj., ECF No. 54. Defendants have previously responded to Plaintiffs’ constitutional arguments but do not devote substantial time to Plaintiffs’ public health representations. *See* Defs.’ Mot. to Dismiss, ECF No. 33; Defs.’ Opposition to Pls.’ Mot. for Prelim. Inj., ECF No. 34; Defs.’ Mot. for Summ. J., ECF No. 71; *see also Triad Int’l Maint. Corp. v. S. Air Transp., Inc.*, No. 2:04-CV-1200, 2005 WL 1917512, at *2 (S.D. Ohio Aug. 10, 2005) (finding that even where parties are well represented to defend their positions, it is appropriate to grant leave for *amici* “to provide information and/or a perspective that can assist the Court in addressing the important issues in [the] case”). The attached brief by proposed *amici* provides the Court a detailed analysis of public health research on the effects of high prescription drug prices on public health, justifying the substantial public policy need for the Program. Proposed *amici* also explain why drug manufacturers’ warnings regarding the negative effects of these new rules on public health are exaggerated, considering longstanding concerns about the nature and scope of drug manufacturers’ investment in prescription drug development. *Amici* wish to make clear that they do support this Program and do not support drug manufacturers’ efforts to end it.

CONCLUSION

For these reasons, the Court should enter the attached Proposed Order granting leave to proposed *amici* to file the attached brief.

Dated: December 19, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation set forth in the Court's local rules and court procedures because it does not exceed the page requirements mandated by local rules.

Dated: December 19, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of December 2023, the foregoing motion was served electronically on all parties via the Court's CM/ECF system.

Dated: December 19, 2023

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